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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,896	10/19/2000	Mark H. Theno	1335.001US1	7633

7590

08/14/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/14/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/691,896

Applicant(s)

THENO, MARK H.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,10-14,17-31 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-14,17-31 and 38-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 3-8, 10-14, 17-31 and 38-41 are pending. The Amendment filed 4/22/02, cancelled claims 2, 9, 15, 32-37, amended claims 1, 3, 5, 6, 10-11, 13-14, 17-25, 29, 38, and added claims 40-41.

The Petition to Revive from Abandonment was granted on May 13, 2002.

#### ***Response to Arguments***

Applicant's arguments with respect to claim 1-14, 16-31 and 38-39 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 10, 11, 24-25, 29, 38, 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "a vapor emitting material stored within the cellular structure comprising the vapor emitting portion" in claim 1 (lines 4-5) is vague and indefinite, as it is confusing. How can the cellular structure comprise the vapor emitting portion, when the vapor emitting portion comprises the cellular structure?

(ii) Claim 5 is vague and indefinite, as it is confusing. Does the vapor emitting portion comprise the cellular structure and further comprises a pad, or does the vapor emitting portion comprise the cellular structure, wherein the cellular structure comprises a pad?

(iii) The phrase "a vapor emitting material received by the cells of the foam pad" in claim 10 (line 6) is vague and indefinite, as it is confusing. What does it mean that the vapor emitting material is received? Does it start elsewhere and then make its way to the pad?

(iv) The terms "cellular structure", "cell" in claims 1, 5, 10, 11, 24-25, 29, 38, and 40-41, is vague and indefinite, as it is not clear what this term means. The specification does not further define this term and one of ordinary skill in the art would not be apprised of its meaning.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 10-14, 17-31, 38-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Cronk et al. (6,244,265) in view of Crotty (6,296,869) and Berthold et al. (6,399,091).

Cronk et al. teach adhesively applied external nasal strips containing medications and fragrances. Disclosed is a nasal strip which includes an elongated substrate, which may be a flexible, fabric-like member or a resilient member. Fragrances and medications are disposed in the elongated substrate by absorption of the active ingredients into the fabric or pores of an absorbent layer, or by coating a top or bottom surface of one layer of the strip. The active ingredient is separated by a separate layer from the adhesive layer facing the skin of the wearer. A release strip, such as silicone or wax coated craft paper, can be added over the adhesive layer. Between the backing layer and the elongated substrate is a resilient member comprised of a flexible, woven or non-woven layer that transmits air and perspiration vapor easily. The

elongated substrate is disclosed as comprising polyester, polyethylene or polypropylene. The reference lacks a hydrogel base. See Figs 1-7.

Crotty et al. teaches an adhesive cosmetic patch containing alpha or beta hydroxy acids. The dermal adhesive strip comprises a flexible substrate and a hydrogel adhesive. Polyethylene terephthalate, polypropylene and polyethylene are disclosed as comprising the flexible substrate. Polyacrylic acid, polyvinylpyrrolidone and others are disclosed as comprising the hydrogels. The hydrogels are disclosed as coherent, three-dimensional aqueous polymer systems capable of absorbing water without liquefying. See abstract; Col. 3, lines 10-46.

Berthold teach that hydrogels possess good biological compatibility, especially when applied for a prolonged period of time, and further teach that hydrogels are characterized by the fact that they are rigid-elastic bodies adapted to the contours of sites of the human body. Packaging the hydrogels is disclosed. See Col. 1, line 65-Col. 2, line 33; Col. 7, lines 15-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the hydrogel base of Crotty et al. to the nasal strips of Cronk et al. because a) Crotty et al. and Cronk et al. are both directed to adhesive strips comprising active agents and flexible layers; b) Cronk et al. teach hydrogels as absorbing great amounts of water and Berthold et al. teach hydrogels as possessing good biological compatibility and as adapted to the contours of the body; thus, adding hydrogels to the nasal strips of Cronk et al. would result in strips that a) last longer because the hydrogels are able to absorb moisture from the nose, thereby prolonging the adhesive effect, and because the hydrogel has good compatibility with the skin, thereby decreasing irritation to the user, and; b) are more effective, as they adapt to the contours of the nose.

### ***Unexpected Results***

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, there are no unexpected results.

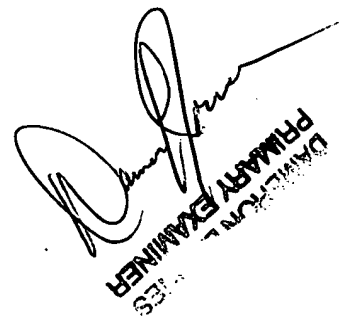
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell S. Travers can be reached on (703)308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
August 7, 2002



LAUREN Q WELLS  
PRIMARY EXAMINER